Applicant's election without traverse of Group I, claims 1-19, 22-24, 27 and 28 in the reply filed on August 31, 2011 is acknowledged. Claim 29 has been withdrawn from considered.

The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a). While applicant filed IDS July 24, 2006, there is no copy of the cited reference in the present application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tonjes et al. J. Virology, 1999, Vol. 73, pp. 987-9195

Tonjes teaches a VLP comprising HML-2 gag polypeptides (page 9193, col. 2, parag. 4, line 7 to page 9194, col. 1, line 1.) Thus Tonjes clearly anticipates the claimed invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zur Megede et. al. J. Virology, 2000, p. 2628-2635, Tonjes et al. J. Virology, 1999, Vol. 73, pp. 987-9195 and Boese et al. FEBS Letters, 2001, Vol. 493, pp. 117-121.

Zur Megede teaches an expression plasmid pCMVKm2 containing a cytomegalovirus (CMV) immediate-early enhancer/promoter and a bGH terminator, an SV40 origin of replication and a kanamycin^{r} selectable marker gene (page 2629, col. 1, parag. 1, lines 15-20). Zur Megede further teaches the delivery of plasmid to mice to determine the production of gag antibodies (page 2632, col. 2, lines 15-18 and parag. 1,

line 1 to page 2633, col. 1, line 5). The in vivo delivered plasmid is a pharmaceutical composition.

Tonjes teaches an expression plasmid comprising an IRES (page 9189, col. 1, parag. 3, lines 9-13.) Tonjes further teaches a cORF sequence from chromosome 22 (page 9187, col. 2, parag. 1, lines 4-7.)

Boese teaches plasmids comprising an HERV-K cORF gene (page 118, col. 1, parag. 1, lines 1-14). These plasmids contain a pBR origin of replication (bacterial) (page 118, col. 1, parag. 1, lines 6.).

Thus, at the time of the instant invention, it would have been obvious to the ordinary artisan to combine the teachings of zur Megede, Tonjes and Boese to produce the claimed vector to produce greater quantities of cORF polypeptide and deliver the vector to a mouse to raise an immune response. CMV was recognized as a strong promoter, so the selection of pCMVkm2 would have been obvious as would have been its modification with the addition of an IRES, which also enhances expression. A bacterial origin of replication would have been known to be preferred for in vivo delivery of the plasmid. Based on the teachings of the cited prior art, the ordinary artisan would have found the invention as claimed obvious.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zur Megede et. al. J. Virology, 2000, p. 2628-2635, Tonjes et al. J. Virology, 1999, Vol. 73, pp. 987-9195 and Boese et al. FEBS Letters, 2001, Vol. 493, pp. 117-121 as applied to claim 1 above, and further in view of Herbst et al. American J. Pathol., 1996, Vol. 149, pp. 1727-1735.

Herbst teaches seminoma patients exhibit increased titers of HERV-K specific antibodies (page 1731, col. 2, parag. 2, lines 1-3 and line 5 to page 1732, col. 1, line 3

Thus at the time of the instant invention, it would have been obvious to the ordinary artisan to modify Megede, Tonjes and Boese by delivery of the plasmid pCMVkm2 containing an HERV-K cORF gene to mice to obtain an immune response to prostate cancer patients whose serum contains gag antibodies as taught by Herbst to determine an immune response.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. Aids Research Human Retrovir., 1996, Vol. 13, pp. 393-400 in view of Tonjes et al. J. Virology, 1999, Vol. 73, pp. 987-9195.

Klein teaches the immunization of human with a HIV-1 Gag VLP results in gag specific CTL responses (page 396, col. 1, parag. 1, lines 7-10.)

Tonjes teaches a VLP comprising HML-2 gag polypeptides (page 9193, col. 2, parag. 4, line 7 to page 9194, col. 1, line 1.)

Thus at the time of the instant invention, it would have been obvious to the ordinary artisan to modify Klein by administering the VLP taught by Tonjes to raise an immune response.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rudolf et al. J. Immun., 2001, Vol. 166, pp. 5917-5925 and Tonjes et al. J. Virology, 1999, Vol. 73, pp. 987-9195 in view of Herbst et al. American J. Pathol., 1996, Vol. 149, pp. 1727-1735.

Rudolf teaches L1L2-E7 VLPs for the treatment of cervical cancer (page 5921-5922, bridg. Sent.)). further states VPLs have been shown to be highly immunogenic in vivo animal studies as well as human trials (page 5922, col. 1, lines 1-3.)

Tonjes teaches a VLP comprising HML-2 gag polypeptides (page 9193, col. 2, parag. 4, line 7 to page 9194, col. 1, line 1.)

Herbst teaches seminoma patients exhibit increased titers of HERV-K specific antibodies (page 1731, col. 2, parag. 2, lines 1-3 and line 5 to page 1732, col. 1, line 3

Thus at the time of the instant invention, it would have been obvious to the ordinary artisan to modify Rudolf by the delivery of VLPs containing HML-2 gag polypeptides taught by Tonjes to prostate cancer patients whose serum contains gag antibodies as taught by Herbst to determine an effect on disease progression.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/
Primary Examiner, Art Unit 1632

November 10, 2011